Press Release

Stockholm, Sweden, June 19, 2023

Mendus receives ATMP certificate from European Medicines Agency supporting its lead pipeline program vididencel

POSITIVE RECOMMENDATION BY COMMITTEE FOR ADVANCED THERAPIES CONFIRMS QUALITY OF THE MANUFACTURING PROCESS AND PRECLINICAL DATA SUBMITTED

Mendus AB ("Mendus" publ; IMMU.ST), a biopharmaceutical company focused on immunotherapies addressing tumor recurrence, today announced that the company has been granted an Advanced Therapy Medicinal Product (ATMP) certificate following a review of manufacturing quality and non-clinical data for its lead pipeline program vididencel by the European Medicines Agency (EMA).

The purpose of the ATMP certification is to provide a structured assessment and guidance to small and medium-sized enterprises (SMEs) developing advanced therapies, which include cell and gene therapies. At the conclusion of the evaluation, a certificate may be issued by the EMA upon the recommendation of the Committee for Advanced Therapies (CAT), confirming the quality of the manufacturing process and preclinical data submitted for ATMP review. Although this certification is not a requirement for a future application for marketing authorization, it affirms that manufacturing quality and non-clinical development has been performed in accordance with regulatory guidelines, taking into consideration the stage of product development.

"The ATMP certification by the EMA is a clear validation of our investments into manufacturing and process development and increases the value of our lead pipeline product vididencel significantly," said Leopold Bertea, PhD, Chief Technology Officer of Mendus. "The ATMP certificate now granted will build an excellent basis for the next steps we have planned and puts vididencel on a solid path towards late-stage development and commercialization preparedness."

Vididencel is currently being evaluated in AML and ovarian cancer as a potential maintenance therapy to reduce tumor recurrence. Vididencel is an intradermal vaccine derived from the Company's proprietary DCOne leukemic cell line. In December 2022, the Company announced positive results from the ADVANCE II study in AML. The analysis demonstrated the potential of vididencel to control measurable residual disease (MRD) and extend durable relapse-free survival in the majority of patients. Mendus expects to present a next survival read-out of the ADVANCE II trial in the fourth quarter of 2023.

Mendus will provide an update on vididencel via a public webcast on Tuesday, June 27, 2023 at 10:00 CET covering the clinical trial strategy, and other key elements of the development path for vididencel including the recently announced manufacturing alliance with NorthX Biologics.

ABOUT MENDUS AB (PUBL)

Mendus is dedicated to changing the course of cancer treatment by addressing tumor recurrence and improving survival outcomes for cancer patients, while preserving quality of life. We are leveraging our unparalleled expertise in allogeneic dendritic cell biology to develop an advanced clinical pipeline of novel, off-the-shelf, cell-based immunotherapies which combine clinical efficacy with a benign safety profile. Based in Sweden and The Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST. http://www.mendus.com/

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